IN THE UNITED STATES DISTRICT COURT FOR THE
MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

RUTH SMITH, Individually and as Widow for the Use and Benefit of Herself and the Next Kin of Richard Smith, Deceased,	)	
Plaintiff,	)	Civil No. 3:05-0444
	)	Judge Aleta A. Trauger
v.	)	(Dist. Of MA No. 1:05-cv-11515PBS)
PFIZER, INC., *et al.*,	)	
Defendants.	)	

DEFENDANTS' SPECIAL REQUESTS FOR JURY INSTRUCTIONS

Defendants, Pfizer Inc ("Pfizer") and Warner-Lambert Company LLC ("Warner-Lambert") (collectively, "Defendants"), by and through their undersigned counsel, pursuant to this Court's Pretrial Order of April 30, 2010, hereby propose that the instructions identified or set forth in the attachments hereto be given to the jury before and following the trial of this matter.

Defendants have conferred with Plaintiff's counsel regarding these proposed instructions, as well as Plaintiff's proposed instructions. Both sides agree that Tennessee Pattern Jury Instruction § 10.02 (Adequacy of Warning) and Tennessee Pattern Jury Instruction § 14.31 (2009) (Present Cash Value – Wrongful Death) should be given; but not on the accompanying instructions necessary to give context to PJI 10.02 and 14.31. Agreement was not reached on the remaining instructions proposed by Defendants or Plaintiff.

Defendants object to Plaintiff's proposed jury instructions as providing inaccurate or incomplete instructions regarding the relevant law. In addition, Plaintiff's proposed instructions include several claims that were never pled or which have been dismissed (such as claims for affirmative misrepresentations, negligent misrepresentation, and negligent infliction of emotional distress). Defendants further note that Plaintiff's proposed instructions fail to advise the jury that Plaintiff must satisfy the requirements of Tennessee's Product Liability Act as a threshold to

recovery under each of Plaintiff's claims.

Without waiving any other objections to Plaintiff's proposed instructions, Defendants specifically object to Plaintiff's proposed instructions on "Negligence: Violation of a criminal statute" and "Violation of Safety Standards" as both legally and factually incorrect for several reasons. First, the authority cited in support of Plaintiff's proposed instruction on violation of a criminal statute does not support it. In *Harden v. Danek Medical, Inc.*, 985 S.W.2d 449 (Tenn. Ct. App. 1999), the court *declined* to reach the issue of whether alleged violations of the Food, Drug and Cosmetic Act ("FDCA") can form the basis of a negligence *per se* claim, noting the split in authority on this issue. *See id.* at 453. In *Gentry v. Hershey Co.*, ___ F. Supp. 2d ___, 2010 WL 457538 (M.D. Tenn. Feb. 3, 2010), the court recently explained that "the Sixth Circuit has held that there is no private cause of action for violation of the [FDCA] and therefore no basis for a negligence per se claim linked to an alleged violation of its provisions." *Id.* at *11 (citing *Kemp v. Medtronic, Inc.*, 231 F.3d 216, 236 (6th Cir. 2000)). Moreover, the *Harden* court specifically held that even if violations of the FDCA could give rise to a negligence *per se* claims, alleged off-label marketing could not support such a claim because any such violation did not proximately cause the injury complained of. *See Harden*, 985 S.W.2d at 453 (dismissing negligence *per se* claims).[1]

More importantly, in the context of this case, instructing a jury that they may consider a "violation" of a safety statute as evidence of negligence is inappropriate. There has been no determination by the FDA that Defendants violated the Food Drug and Cosmetic Act ("FDCA") or any FDA regulation by not including a statement regarding suicide in the warnings section of the Neurontin label in 2004 or earlier. To the contrary, the FDA specifically considered data on suicide, approved the Neurontin label as adequate and required Defendants to use the approved

[1] For the reasons set forth in Defendants' Motion in Limine to Exclude All Evidence of or References to Warner-Lambert Company LLC's Guilty Plea or Any Related Government Investigations or Agreements [MDTenn 125], the plea is wholly irrelevant to any issue in this litigation.

label verbatim. As a result, the jury should be instructed, as proposed herein and consistent with the Tennessee Product Liability Act, that there is a presumption that Neurontin was not defective or unreasonably dangerous.

Accordingly, Defendants submit these proposed instructions conditionally and without waiver of their right to contend at trial that certain instructions should not be given because the evidence admitted does not warrant submitting some or all of the issues to the jury and without waiver of its right to request additional or modified instructions in light of the record developed at trial, rulings by this Court, or other subsequent developments.

Dated: May 13, 2010

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this the 13th day of May 2010, I electronically filed the foregoing document with the Clerk of the Court, United States District Court for the Middle District of Tennessee, using the CM/ECF system. True and correct copies of the foregoing documents are being served via the Court's CM/ECF system on the following:

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PROPOSED INSTRUCTION 1

TENNESSEE PRODUCT LIABILITY ACT

Each of the plaintiff's claims against the defendants are what are referred to as product liability claims. Tennessee's product liability laws provide that one who manufactures or sells a defective or unreasonably dangerous product is responsible to the ultimate consumer of the product for physical harm caused to the consumer or the consumer's property if: (1) The manufacturer or seller is engaged in the business of manufacturing or selling such a product; and (2) it is expected to and does reach the user or consumer without substantial change in the condition in which it was manufactured. A product is "defective" if it is unsafe for normal or reasonably anticipated handling and use. A product is "unreasonably dangerous" if it would not be offered for sale by a reasonably careful manufacturer or seller who knew of its dangerous condition.

A "manufacturer" is a person or company that designs, fabricates, produces, compounds, processes or assembles any product or its component parts. The word "seller" includes a retailer, wholesaler, or distributor. A seller is any individual or organization in the business of selling a product, either for resale or for use or consumption. A manufacturer or seller of a product is not responsible for any injury to person or property caused by the product unless the product is determined to be in a defective condition or is unreasonably dangerous at the time it left the manufacturer's or seller's control.

A manufacturer is not required to make the product "perfect, or render the product accident proof or incapable of causing injury."[2] The mere fact that an accident or injury happened, standing alone, does not permit the jury to draw the inference that the product was

[2] *Curtis v. Universal Match Corp.*, 778 F. Supp. 1421, 1430 (E.D. Tenn. 1991), *aff'd mem. sub nom. Curtis v. Pope & Talbot, Inc.*, 966 F.2d 1451 (6th Cir. 1992).

defective or unreasonably dangerous.[3] In determining whether plaintiff has met her burden of proving that Neurontin was "defective" or "unreasonably dangerous" you should consider also the customary designs, methods, standards and techniques of manufacturing, inspecting and testing by other manufacturers or sellers of similar products.[4]

Plaintiff has the burden of proving that Neurontin was defective or unreasonably dangerous to recover under all of the theories she has alleged. In this case, plaintiff claims that the defendants failed to provide adequate warnings about Neurontin and that it was defendants' failure to provide such warnings that rendered Neurontin defective or unreasonably dangerous.[5]

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[3] 3 Kevin F. O'Malley et al., *Federal Jury Practice and Instructions* § 120.20 (5th ed. 2000) (modified); *see also Lee v. Metro. Gov't*, 596 F. Supp. 2d 1101, 1130 (M.D. Tenn. 2009) (Trauger, J.); *Burgess v. Floyd*, No. 01A01-9609-CV-00436, 1997 WL 249955, at *4 (Tenn. Ct. App. May 14, 1997).

[4] *Tennessee Pattern Jury Instructions* § 10.01 (2009) (modified). For the reasons stated in Defendants' Pre-Trial Brief, the instruction has been modified to eliminate reference to the consumer expectation test. *See Brown v. Raymond Corp.*, 432 F.3d 640, 644-45 (6th Cir. 2005). Alternatively, if the jury is instructed regarding the consumer expectation test, it should be instructed that, in cases involving prescription drugs, an "ordinary consumer" is a physician who prescribes it with the ordinary knowledge common to physicians experienced with the drug and knowledgeable as to its characteristics. *See Pittman v. Upjohn Co.*, 890 S.W.2d 425, 430 (Tenn. 1994); *Harden v. Danek Med., Inc.*, 985 S.W.2d 449, 451 (Tenn. Ct. App. 1998).

In addition, the Defendants suggest that the language from PJI section 10.01 regarding the state of scientific knowledge as of the date of marketing will make more sense to the jury if it is included in the instruction on adequacy of warnings.

[5] In the event that the jury is instructed under multiple theories of recovery, notwithstanding the common factual predicate of Plaintiff's failure to warn claim, Defendants respectfully submit that the jury should be instructed that the requirements of the Tennessee Product Liability Act are prerequisites to recovery under each theory asserted. *See* Tenn. Code Ann. § 29-28-102(6) (West 2002); *Privette v. CSX Transp., Inc.*, 79 F. App'x 879, 890 (6th Cir. 2003); *Irion v. Sun Lighting, Inc.*, No. M2002-00766-COA-R3-CV, 2004 WL 746823, at *3 (Tenn. Ct. App. Apr. 7, 2004); *Shoemake v. Omniquip Int'l, Inc.*, 152 S.W.3d 567, 572-73 (Tenn. Ct. App. 2003).

PROPOSED INSTRUCTION 2

PRESCRIPTION DRUGS (COMMENT K)

Before explaining the standard by which you must judge whether plaintiff has proven that defendants failed to provide adequate warnings, you need to know that there are some products which, in the present state of human knowledge, are incapable of being made safe for their intended and ordinary use. These are especially common in the field of prescription drugs. Such a product, properly prepared and accompanied by proper directions and warning, is not defective nor is it unreasonably dangerous. The manufacturer of an unavoidably unsafe product, such as a prescription drug, is not liable for injuries arising from the product, if the manufacturer provided adequate warnings on the dangers inherent in the product.[6]

In determining whether defendants' warnings were adequate, you must apply the state of scientific and technological knowledge that was available to the defendants in March 2004, when Richard Smith was prescribed Neurontin. You may not consider any information that became available only after that date on the question of whether the warnings provided with Neurontin were adequate.[7]

For each of her causes of action, therefore, plaintiff must prove:

1) That Neurontin can cause those who take it to commit suicide;

2) That the relationship, if any, between Neurontin and suicide was known, or given the state of scientific and technological knowledge available to the defendants in March 2004, should have been known, when Richard Smith was prescribed Neurontin in March 2004;[8]

3) That the defendants failed to give adequate warnings and instructions to Richard

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[6] *See* Restatement (Second) of Torts § 402A cmt. k (1965); *Harwell v. Am. Med. Sys., Inc.*, 803 F. Supp. 1287, 1300 (M.D. Tenn. 1992); *Pittman v. Upjohn Co.*, 890 S.W.2d 425, 428-29 (Tenn. 1994).

[7] *See Tennessee Pattern Jury Instructions* § 10.01 (2009) (modified); Tenn. Code Ann. § 29-28-105(b) (West 2002).

[8] *See* Tenn. Code Ann. § 29-28-105(b).

Smith's medical providers regarding the relationship, if any, between Neurontin and suicide or suicidal behavior;[9]

4) That the failure, if any, to give adequate warnings and instructions rendered Neurontin defective or unreasonably dangerous as marketed;[10]

5) That Neurontin was a cause-in-fact of Richard Smith's suicide in that he would not have been prescribed Neurontin but for defendants' failure to provide those warnings **and** that Richard Smith would not have committed suicide but for the fact that he was prescribed and took Neurontin;

6) That Neurontin was a legal cause of Richard Smith's suicide in that the Neurontin he took was a substantial factor in his suicide; and[11]

7) That plaintiff has suffered damages as a result.

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[9] *See King v. Danek Med., Inc*, 37 S.W.3d 429, 453 (Tenn. Ct. App. 2000).

[10] *See* Tenn. Code Ann. § 29-28-105(a) (West 2002).

[11] *See Goins v. Clorox Co.*, 926 F.2d 559, 561 (6th Cir. 1991); *Whitehead v. Dycho Co.*, 775 S.W.2d 593, 600 (Tenn. 1989).

PROPOSED INSTRUCTION 3

ADEQUACY OF WARNING

Where proper instructions for use and an adequate warning of hazards are given, the seller may reasonably assume that they will be read and followed. Thus, a product is not in a defective condition nor is it unreasonably dangerous, if (1) the manufacturer or seller has given proper instructions for the use of a product and an adequate warning of the dangers associated with the use or misuse of the product; and (2) the product is safe for use if the instructions and warning are read and followed.

Adequate and proper instructions establish procedures for efficient use and for avoiding danger. An adequate warning is one calculated to call to the attention of a reasonably careful person the nature and extent of the danger involved in using or misusing the product.

In preparing instructions and warnings, manufacturers and sellers must take into account, among other things, the intended or reasonably expected users or consumers of the product. Where a danger or hazard is apparent to the ordinary user, a product is not unreasonably dangerous or defective even if no warning is given.[12]

[12] *Tennessee Pattern Jury Instructions* § 10.02 (2009).

PROPOSED INSTRUCTION 4

DUTY OWED TO PHYSICIAN (LEARNED INTERMEDIARY DOCTRINE)

The defendants satisfied their duty to adequately warn of dangers and instruct for safe use if they furnished adequate warnings and instructions for prescribing medical providers. The physician or physician's assistant, as a learned intermediary, is the person best qualified to make an informed choice about appropriate treatment and patient communications after evaluating the benefits of a particular drug against the risk of harm from its use.[13]

[13] *See Harwell v. Am. Med. Sys., Inc.*, 803 F. Supp. 1287, 1299 (M.D. Tenn. 1992); *Pittman v. Upjohn Co.*, 890 S.W.2d 425, 428-29 (Tenn. 1994); *Laws v. Johnson*, 799 S.W.2d 249, 254 (Tenn. Ct. App. 1990).

PROPOSED INSTRUCTION 5

FOOD AND DRUG ADMINISTRATION – REGULATORY APPROVAL

Compliance by a manufacturer or seller with any federal or state statute or administrative regulation existing at the time a product was manufactured and prescribing standards for design, inspection, testing, manufacture, labeling, warning or instructions for use of a product, raises a rebuttable presumption that the product is not in an unreasonably dangerous condition in regard to matters covered by these standards.[14]

It is undisputed that the package insert and package labeling for Neurontin at the time it was prescribed to Richard Smith were approved by the FDA. You are instructed that under federal statutes, the FDA can approve labeling only if it concludes that the labeling (1) is supported by essential scientific evidence and (2) is supported by adequate evidence of safety and effectiveness. You are further instructed that the FDA had the sole authority to require that a manufacturer provide warnings regarding off-label uses of a prescription drug, if the drug is commonly prescribed for a disease or condition, and there is lack of substantial evidence of effectiveness for that disease or condition, and such usage is associated with serious risk or hazard.[15] Under Tennessee law, the FDA's approval of the Neurontin label creates a rebuttable presumption that it was adequate.[16]

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[14] Tenn. Code Ann. § 29-28-104 (West 2002).

[15] *See* 21 C.F.R. § 201.57(e) (2004).

[16] *See* 21 U.S.C. §§ 321, 331-337, 351-360n; 21 U.S.C. 360aaa to 360aaa-6 (2006) (effectiveness terminated 2006); Tenn. Code Ann. § 29-28-104.

PROPOSED INSTRUCTION 6

OFF-LABEL USE

At the time Richard Smith's physicians prescribed Neurontin for him in March 2004, the FDA had approved Pfizer's applications to market Neurontin as a treatment for two conditions. The two approved conditions were partial seizures, a form of epilepsy, and postherpetic neuralgia, a form of pain. The two approved conditions are listed in the "Indications and Usage" section of the labeling approved by the FDA. Use of Neurontin to treat those conditions is known as "on-label" use. Use of Neurontin to treat other conditions is known as "off-label" use.

Richard Smith's physician's prescriptions of Neurontin were for treatment of an off-label condition. That does not mean that the prescriptions for Richard Smith were in any way improper or illegal. Tennessee law permits doctors to prescribe drugs to treat "off-label" conditions. The FDA does not regulate the practice of medicine, and FDA policies recognize the right of doctors to prescribe medications for off-label uses.[17]

[17] *Richardson v. Miller*, 44 S.W.3d 1, 12-13 (Tenn. Ct. App. 2000); *see also* 21 U.S.C. § 396 ("Nothing in [the Federal Food, Drug and Cosmetic Act] shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship."); *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001) ("[T]he 'FDA itself recogniz[es] the value and propriety of off-label use . . . .'" (citation omitted)); *Hood ex rel. Mississippi v. Eli Lilly & Co.* (In re Zyprexa Prods. Liab. Litig.), 671 F. Supp. 2d 397, 415 (E.D.N.Y. 2009) ("Some off-label uses of a prescription drug may be medically necessary."); *Ortho Pharm. Corp. v. Cosprophar, Inc.*, 32 F.3d 690, 692 (2d Cir. 1994); *Sita v. Danek Med., Inc.*, 43 F. Supp. 2d 245, 262 n.13 (E.D.N.Y. 1999).

PROPOSED INSTRUCTION 7

NEGLIGENCE[18]

Negligence is the failure to use ordinary or reasonable care. It is either doing something that a reasonably careful person would not do, or the failure to do something that a reasonably careful person would do, under all of the circumstances in this case. A person may assume that every other person will use reasonable care, unless a reasonably careful person has cause for thinking otherwise.[19]

A supplier who knows or reasonably should know that a product is likely to be dangerous for its intended use or foreseeable misuse has a duty to use reasonable care to warn of the product's danger or to reveal its unsafe condition. Warnings should be given to those persons whom the supplier should reasonably expect to use or to handle the product or be endangered by its use or handling, if the supplier reasonably should believe those persons would not realize the danger without the warnings. The failure to fulfill this duty is negligence.[20]

In making this determination, you must apply the state of scientific and technological knowledge available to the defendants in March 2004, when Richard Smith was prescribed Neurontin. You may not consider any information that became available only after that date on the question of whether the warnings provided with Neurontin were adequate.[21]

In order to meet her burden of proof on her negligence claim, plaintiff must establish by a

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[18] As discussed in Defendants' Pre-Trial Brief, each of Plaintiff's claim is predicated upon a product manufacturer's duty to warn of known and foreseeable risks of its product and each is, therefore, governed by the Tennessee Product Liability Act. Consideration should be given, therefore, to whether the jury should be instructed on different theories of liability. *See* Restatement (Third) of Torts: Products Liability § 2 cmt. n (1998) ("[T]wo or more factually identical . . . failure-to-warn claims should not be submitted to the trier of fact in the same case under different doctrinal labels.").

[19] *Tennessee Pattern Jury Instructions* § 3.05 (2009) (Definition of Negligence).

[20] *Tennessee Pattern Jury Instructions* § 10.12 (2009) (Supplier's Duty to Warn).

[21] *See* Tenn. Code Ann. § 29-28-105(b) (West 2002).

preponderance of the evidence each of the following elements:

1) That Neurontin can cause those who take it to commit suicide;

2) That the defendants owed a duty of care to warn prescribing physicians about risks of Neurontin that they were aware of or in the exercise of reasonable care should have been aware of;

3) That as of March 2004, defendants were aware, or in the exercise of reasonable care, should have been aware that Neurontin could cause individuals who took it to commit suicide;

4) That defendants breached their duty by failing to provide warnings in March 2004 that Neurontin could cause individuals who took it to commit suicide;

5) That defendants' failure to provide those warnings rendered Neurontin "defective" or "unreasonably dangerous" in March 2004;

6) That Neurontin was a cause-in-fact of Richard Smith's suicide in that he would not have been prescribed Neurontin but for defendants' failure to provide those warnings **and** that Richard Smith would not have committed suicide but for the fact that he was prescribed and took Neurontin;

7) That Neurontin was a legal cause of Richard Smith's suicide in that the Neurontin he took was a substantial factor in his suicide; and

8) That plaintiff has suffered damages as a result.

PROPOSED INSTRUCTION 8

FRAUDULENT CONCEALMENT[22]

In this case, the plaintiff claims that the defendants misrepresented the safety of Neurontin by failing to disclose information to the decedent's physicians regarding the risk of suicide or suicidal behavior. The defendants deny that they failed to disclose any important fact to the decedent's physicians.

The plaintiff may recover money damages from the defendants if and only if she proves that (1) the defendants concealed or suppressed a material fact; (2) the defendants were under a duty to disclose the fact to Mr. Smith's physician; (3) the defendants intentionally concealed or suppressed the fact with the intent to deceive Mr. Smith's physician; and (4) Mr. Smith's physician was not aware of the fact and would have acted differently if he or she knew of the concealed or suppressed fact; and (5) as a result of the concealment or suppression of the fact, the plaintiff sustained damage.[23]

A manufacturer has no duty to warn or provide instructions about risks that were not reasonably foreseeable at the time of sale or could not have been discovered by way of reasonable testing prior to marketing the product.[24] The duty to warn extends only to such dangers about which the manufacturer either actually knew or about which it reasonably should have known based upon the state of scientific and technological knowledge available to the manufacturer or seller at the time the product was placed on the market, rather than at the time of injury.[25]

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[22] *See supra* note 18.

[23] *Tennessee Pattern Jury Instructions* § 8.38 (2009) (Misrepresentation by Concealment) (modified to reflect learned intermediary rule); *Chrisman v. Hill Home Dev.*, 978 S.W.2d 535, 538-39 (Tenn. 1998).

[24] *See* Tenn. Code Ann. § 29-28-105(a) (West 2002).

[25] *See* Tenn. Code Ann. § 29-28-105(b) (West 2002).

In order to meet her burden of proof on her fraudulent concealment claim, plaintiff must establish by a preponderance of the evidence each of the following elements:

1) That Neurontin can cause those who take it to commit suicide;

2) That the defendants were aware of that fact in March 2004, before Richard Smith was prescribed Neurontin;

3) That the defendants were under a duty to disclose that fact to the healthcare providers who prescribed Neurontin for Richard Smith;

4) That the defendants intentionally concealed or suppressed the fact that Neurontin can cause those who take it to commit suicide and they did so with the intent to deceive Richard Smith's healthcare providers who prescribed Neurontin for him;

5) That the defendants' intentional concealment of suppression of that fact rendered Neurontin "defective" or "unreasonably dangerous" in March 2004;

6) That those healthcare providers were not aware that Neurontin can cause those who take it to commit suicide and those healthcare providers would not have prescribed Neurontin for Richard Smith had they known that fact;

7) That defendants' concealment was a cause-in-fact of Richard Smith's suicide in that he would not have committed suicide but for the fact that he was prescribed and took Neurontin;

8) That defendants' concealment was a legal cause of Richard Smith's suicide in that the Neurontin he took was a substantial factor in his suicide; and

9) That plaintiff has suffered damages as a result.

PROPOSED INSTRUCTION 9

BREACH OF WARRANTY: NOTICE OF BREACH[26]

In this case plaintiff seeks to establish liability on a breach of warranty. In order to recover for a breach of warranty, the buyer must have given the seller notice of the breach within a reasonable time after the buyer knew or, using reasonable care, should have known of the alleged defect. Determination of a reasonable time depends upon the circumstances and the kind of product involved.

While no particular form of notice is required, it must inform the seller of the alleged breach and the buyer's intent to seek damages. Whether that notice was given within a reasonable time is for you to determine.[27]

[26] *See supra* note 18.

[27] *Tennessee Pattern Jury Instructions* § 10.21 (2009)

PROPOSED INSTRUCTION 10

IMPLIED WARRANTY OF FITNESS

Unless excluded or modified by agreement, there is an implied warranty that goods shall be fit for the particular purpose for which the goods are required if, at the time of sale, the seller has reason to know the purpose and that the buyer is relying on the seller's skill or judgment to select or furnish suitable goods for that purpose.[28]

To prove her claim for breach of implied warranty, plaintiff must prove (1) that defendants were aware of the particular purpose for which Mr. Smith's physicians were prescribing Neurontin to Mr. Smith, (2) defendants knew and that Mr. Smith's physicians were relying on defendants' skill or judgment to select or furnish suitable goods for that particular purpose, (3) Mr. Smith's physicians did, in fact, rely upon the defendants to select or furnish suitable goods, and (4) that Neurontin was not fit for the particular purpose for which it was intended.[29]

A "particular purpose" differs from the ordinary purpose for which the goods are used in that it envisages a specific use by the buyer which is peculiar to the nature of his business whereas the ordinary purposes for which goods are used are those customarily made of the goods in question.[30]

In order to meet her burden of proof on her claim for breach of implied warranty of fitness for a particular use, plaintiff must establish by a preponderance of the evidence each of the following elements:

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[28] *Tennessee Pattern Jury Instructions* § 10.30 (2009).

[29] *See Lee's Home Ctr., Inc. v. Morris*, No. M2004-02158-COA-R3-CV, 2006 WL 1716797, at *4 (Tenn. Ct. App. June 21, 2006); *Jet Printing, LLC v. Deep S. Wholesale Paper Co.*, No. M2001-02582-COA-R3-CV, 2003 WL 152644, at *4 (Tenn. Ct. App. Jan. 23, 2003).

[30] *Lee's Home Ctr., Inc.*, 2006 WL 1716797, at *4 n.5 (quoting Tenn. Code Ann. § 47-2-315 cmt. 2).

1) That Neurontin can cause those who take it to commit suicide;

2) That, as of March 2004, defendants were aware, or in the exercise of reasonable care, should have been aware that Neurontin could cause individuals who took it to commit suicide;

3) That defendants were aware of the particular purpose for which Mr. Smith's healthcare providers were prescribing Neurontin to Mr. Smith;

4) That defendants knew that Mr. Smith's healthcare providers were relying on defendants' skill or judgment to select or furnish suitable goods for that particular purpose;

5) That Mr. Smith's healthcare providers did in fact rely upon defendants to select or furnish suitable goods;

6) That defendants breached the implied warranty of fitness for the particular purpose for which it was intended by failing to warn Mr. Smith's healthcare providers that it could cause people who took it to commit suicide;

7) That defendants' failure to warn rendered Neurontin "defective" or "unreasonably dangerous;"

8) That defendants' breach of that implied warranty was a cause-in-fact of Richard Smith's suicide in that he would not have been prescribed Neurontin but for the fact that he was prescribed and took Neurontin;

9) That defendants' breach of the implied warranty was a legal cause of Richard Smith's suicide in that the Neurontin he was prescribed and took was a substantial factor in his suicide;

10) That plaintiff has suffered damages as a result.

PROPOSED INSTRUCTION 11

CAUSATION

Each of plaintiff's claims requires proof of two types of causation: Cause in fact and legal cause. Cause in fact and legal cause are distinct elements of each of plaintiff's claims and both must be proven by a preponderance of the evidence.[31]

[31] *Tennessee Pattern Jury Instructions* § 3.20 (2009) (Causation) (modified to refer to "each of plaintiff's claims," instead of only negligence).

PROPOSED INSTRUCTION 12

CAUSE-IN-FACT

The defendant's conduct is a cause in fact of the plaintiff's injury if, as a factual matter, it directly contributed to the plaintiff's injury and without it plaintiff's injury would not have occurred. It is not necessary that a defendant's act be the sole cause of plaintiff's injury, only that it be a cause.[32]

Initially, a prescription drug manufacturer's alleged failure to warn cannot be the cause-in-fact of injury unless a different warning would have changed the physician's decision to prescribe the drug.[33]

In addition, to prove cause-in-fact, plaintiff must also prove both general medical causation and specific medical causation. To prove general medical causation, plaintiff must prove by a preponderance of the evidence that the use of Neurontin does generally cause suicide in some people.[34] To prove specific medical causation, plaintiff must prove by a preponderance of the evidence that Richard Smith would not have committed suicide but for the defendants' alleged failure to provide the warnings that plaintiff contends should have been included on the

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[32] *Tennessee Pattern Jury Instructions* § 3.21(2009) (Cause in Fact).

[33] *See King v. Danek Med., Inc.*, 37 S.W.3d 429, 453 (Tenn. Ct. App. 2001); *see also Wheat v. Pfizer, Inc*., 31 F.3d 340, 343 (5th Cir. 1994); *Thomas v. Hoffman-LaRoche, Inc.,* 949 F.2d 806, 814 (5th Cir. 1992); *Odom v. G.D. Searle & Co*., 979 F.2d 1001, 1003-04 (4th Cir. 1992); *Plummer v. Lederle Labs., Div. of Am. Cyanimid Co.*, 819 F.2d 349, 358-59 (2d Cir. 1987); *Nix v. SmithKline Beecham Corp.*, No. CV-06-43-PHX-SMM, 2007 WL 2526402, at *3 (D. Ariz. Sept. 5, 2007); *Fisher v. Bristol-Myers Squibb Co*., 181 F.R.D. 365, 370 (N.D. Ill. 1998); *In re Norplant Contraceptive Prods. Liab. Litig.*, 955 F. Supp. 700, 711 (E.D. Tex. 1997), *aff'd*, 165 F.3d 374 (5th Cir. 1999); *Windham v. Wyeth Labs., Inc.*, 786 F. Supp. 607, 612 (S.D. Miss. 1992); *Vaughn v. G.D. Searle & Co.*, 536 P.2d 1247, 1250-51 (Or. 1975).

[34] *See In re Bextra & Celebrex Mktg. Sales Practices & Prod. Liab. Litig.*, 524 F. Supp. 2d 1166, 1171-72 (N.D. Cal. 2007); *In re Rezulin Prods. Liab. Litig.*, 369 F. Supp. 2d 398, 401-02 (S.D.N.Y. 2005); *In re Norplant Contraceptive Prods. Liab. Litig.*, 215 F. Supp. 2d 795, 830 (E.D. Tex. 2002); *In re Breast Implant Litig.*, 11 F. Supp. 2d 1217, 1224 (D. Colo. 1998).

Neurontin label in 2004.[35]

[35] *See Shouse v. Otis*, 448 S.W.2d 673, 676 (Tenn. 1969); *Mason v. Metro. Gov't*, 189 S.W.3d 217, 221 (Tenn. Ct. App. 2005); *Johnson v. Settle*, No. M1999-01237-COA-R3-CV, 2001 WL 585093, at *6 (Tenn. Ct. App. June 1, 2001); *In re Bextra*, 524 F. Supp. 2d at 1172; *In re Rezulin*, 369 F. Supp. 2d at 402; *In re Breast Implant Litig.*, 11 F. Supp. 2d at 1224.

PROPOSED INSTRUCTION 13

LEGAL CAUSE

If you determine that the defendant's conduct was a cause in fact of the plaintiff's injury – that is, but for (or without) the defendant's conduct the plaintiff would not have been injured, you must also decide whether the defendant's conduct was also a legal cause of the plaintiff's injury, as defined below.

The law in Tennessee sets out two requirements to determine whether an act or omission was a legal cause of the injury or damage.

1. The conduct must have been a substantial factor in bringing about the harm being complained of; and,

2. The harm giving rise to the action could have been reasonably foreseen or anticipated by a person of ordinary intelligence and care.

To be a legal cause of an injury, there is no requirement that the cause be the only cause, the last act, or the one nearest to the injury, so long as it is a substantial factor in producing the injury or damage.

The foreseeability requirement does not require that the person guilty of the wrongful conduct to foresee the exact manner in which the injury takes place or the exact person who would be injured. It is enough that the person guilty of the wrongful conduct could foresee, or through the use of reasonable care, should have foreseen the general manner in which the injury or damage occurred.[36]

In addition, you may not assign any liability to the defendants, on any of the plaintiff's claims, unless plaintiff proves that the defendants' conduct caused Richard Smith to commit suicide as result of delirium or insanity. Defendants' conduct was not the legal cause of

[36] *Tennessee Pattern Jury Instructions* § 3.22 (2009) (modified to make the first sentence contingent and to refer to defendant's conduct, rather than just negligence).

Mr. Smith's death if his suicide resulted from a moderately intelligent power of choice, even if that choice is determined by a disordered mind.[37]

[37] *See MacDermid v. Discover Fin. Servs.*, 488 F.3d 721, 736 (6th Cir. 2007); *Jones v. Stewart*, 183 Tenn. 176, 179, 191 S.W.2d 439, 440 (1946); *Rains v. Bend of the River*, 124 S.W.3d 580, 593-94 (Tenn. Ct. App. 2003).

PROPOSED INSTRUCTION 14

EFFECT OF INSTRUCTION ON DAMAGES

I now turn to the subject of damages. You will only reach the issue of damages if you find that the defendants were negligent and that the defendants' negligence was a proximate cause of the decedent's death. You should not interpret the fact that I have given instructions about the plaintiff's damages as an indication in any way that I believe that the plaintiff should, or should not, win this case. Consider damages only if necessary.[38]

If you decide that the plaintiff is entitled to damages, you must fix an amount that will reasonably compensate her for each for the following elements of claimed loss of harm, if you find it was suffered by the plaintiff and was caused by the act or omission upon which you base your finding of fault.

Each of these elements of damage is separate. You may not duplicate damages for any element by also including that same loss or harm in another element of damage.[39]

[38] *See* Fifth Circuit Pattern Jury Instructions No. 15.1 (2006); *see also* 3 Kevin F. O'Malley et al., *Federal Jury Practice and Instructions* § 106.02 (5th ed. 2000) (modified).

[39] *Tennessee Pattern Jury Instructions* § 14.01 (2009).

PROPOSED INSTRUCTION 15

COMPENSATORY DAMAGES

In this case, suit has been brought for damages alleging the death of Richard Smith was caused by the fault of the defendant. If you decide to award damages, there are two classes of damages you may consider:

First, those damages sustained immediately by the injured party including compensation for the following:

1. The mental and physical suffering actually endured by the injured party between the injury and death; and

2. Reasonable funeral expenses.

You may not speculate as to whether conscious pain and suffering actually did exist between the injury and death. If, however, you find that there was such pain and suffering prior to death, you must award damages for it.

The second class of damages that may be awarded is the present cash value of the pecuniary value of the life of the deceased. In determining this value, you should take into consideration the following factors:

1. The age of the deceased;

2. The condition of health of the deceased;

3. The life expectancy of the deceased;

4. The strength and capacity of the deceased for work and for earning money through skill in any art, trade, profession, occupation, or business;

5. The personal habits of the deceased as to sobriety and industry; and

6. The reasonable value of the loss of consortium suffered by the wife [and children] of the deceased.

"Consortium" is a legal term consisting of several elements. It includes both tangible services provided by a family member, as well as intangible benefits each family member

receives from the continued existence of other family members. Such intangible benefits include love, affection, attention, education, guidance, care, protection, training, companionship and cooperation and, in the case of a spouse, sexual relations, that the wife [and children] would reasonably be certain to have received during the life of the deceased.

[In determining whether to award damages for loss of consortium for the death of a parent, you should consider the age of the children, closeness of relationship, dependence and any other factors that reflect upon the relationship between parent and child.]

In weighing these factors, you should consider the fact that expectancy of life is, at most, a probability based upon experience and statistics. You should be mindful of the possibility that the earnings of an individual are not always uniform over a period of time. You should consider not only the most optimistic expectations of the future, but also the most pessimistic, and all of the uncertainties between the extremes.

Finally, when determining the amount of damages based upon life expectancy and earning capacity, you should deduct the present cash value of the deceased's living expenses had the deceased lived. These living expenses are those that under the deceased's standard of living would have been reasonably necessary to keep the deceased in such a condition of health and well-being as to maintain the capacity to earn money.[40]

[40] *Tennessee Pattern Jury Instructions* § 14.30 (2009) (Wrongful Death). For the reason's stated in Defendants' Motion in Limine to Exclude Evidence of Any Loss of Consortium Damages Suffered by Decedent's Children [MDTenn 104, 105], Defendants object to submission of parental consortium to the jury.

PROPOSED INSTRUCTION 16

PRESENT CASH VALUE

I have used the expression "present cash value" in these instructions concerning damages for certain losses that may be awarded in this case. In determining the pecuniary value of the life of the decedent Richard Smith, you must adjust the award to allow for the reasonable earning power of money and the impact of inflation. "Present cash value" means the sum of money needed now, which when added to what that sum may reasonably be expected to earn in the future when invested, would equal the amount of damages at the time in the future when the earnings would have been received, living expenses incurred and the loss of consortium experienced. You should also consider the impact of inflation, its impact on wages and its impact on purchasing power in determining the present cash value of future damages.[41]

[41] *Tennessee Pattern Jury Instructions* § 14.31 (2009) (Present Cash Value – Wrongful Death).

PROPOSED INSTRUCTION 17

LIFE EXPECTANCY

The life expectancy read to you is not conclusive but is an average life expectancy of persons who have reached a certain age. You should be aware that many persons live longer, and many die sooner, than the average. This figure may be considered by you in connection with other evidence relating to the probable life expectancy of the decedent, including evidence of the decedent's health, occupation, habits and other activities.[42]

[42] *Tennessee Pattern Jury Instructions* § 14.53 (2009) (Life Expectancy).

PROPOSED INSTRUCTION 18

PUNITIVE DAMAGES

Plaintiff has asked that you make an award of punitive damages, but this award may be made only under the following circumstances. You may consider an award of punitive damages only if you find that the plaintiff has suffered actual damage as a legal result of the defendant's fault and you have made an award for compensatory damages.

Punitive damages are to be awarded only in the most egregious of cases.[43] The purpose of punitive damages is not to further compensate the plaintiff but to punish a wrongdoer and deter others from committing similar wrongs in the future. Punitive damages may be considered if, and only if, the plaintiff has shown by clear and convincing evidence that a defendant has acted either intentionally, recklessly, maliciously, or fraudulently.

Clear and convincing evidence is a different and higher standard that preponderance of the evidence. It means that the defendant's wrong, if any, must be so clearly shown that there is no serious or substantial doubt about the correctness of the conclusions drawn from the evidence.

A person acts intentionally when it is the person's purpose or desire to do a wrongful act or to cause the result. A person acts recklessly when the person is aware of, but consciously disregards a substantial and unjustifiable risk of injury or damage to another. Disregarding the risk must be a gross deviation from the standard of care that an ordinary person would use under all the circumstances. A person acts maliciously when the person is motivated by ill will, hatred or personal spite. A person acts fraudulently when: (1) the person intentionally either misrepresents an existing material fact or causes a false impression of an existing material fact to

[43] *See Goff v. Elmo Greer & Sons Constr. Co.*, 297 S.W.3d 175, 197 (Tenn. 2009) ("[T]rial courts would do well to explicitly charge that punitive damages are reserved for egregious conduct as a way of crystalizing the point that punitive damages do indeed represent 'strong medicine.'"), *cert. denied*, No. 09-921, 2010 WL 390377 (U.S. Mar. 22, 2010); *Hodges v. S.C. Toof & Co.*, 833 S.W.2d 896, 901 (Tenn. 1992).

mislead or to obtain an unfair or undue advantage; and (2) another person suffers injury or loss because of reasonable reliance upon that representation.[44]

[44] *Tennessee Pattern Jury Instructions* § 14.55 (2009) (Punitive Damages).

PROPOSED INSTRUCTION 19

PUNITIVE DAMAGES – AMOUNT

If you decide that the plaintiff is entitled to punitive damages, you must also decide the amount, if any, of those damages. The plaintiff has the burden of proving by a preponderance of the evidence the amount of punitive damages that you should award.

Punitive damages are to be awarded only in the most egregious of cases.[45] In deciding whether they should be imposed in this case, you should do so with great caution and should award them only if and to the extent necessary to achieve the proper amount of deterrence and punishment. Whether to impose punitive damages is discretionary, which means that a plaintiff never has a right to an award of punitive damages and you are not required to award them under any circumstance. The fact that the Court is instructing you on the law of punitive damages is not meant in any way to influence your decision whether it is necessary and appropriate to impose them. Any amount of punitive damages you award must not exceed the amount that you find the plaintiff has proven is reasonably required to vindicate Tennessee's legitimate interest in punishment and deterrence, if any, for the wrongful conduct that harmed the plaintiff in this case.[46] In addition, if punitive damages are awarded in any amount, that amount must be both reasonable and proportionate to the amount of harm to the plaintiff and to the amount of

[45] *See Goff v. Elmo Greer & Sons Constr. Co.*, 297 S.W.3d 175, 197 (Tenn. 2009) ("[T]rial courts would do well to explicitly charge that punitive damages are reserved for egregious conduct as a way of crystalizing the point that punitive damages do indeed represent 'strong medicine.'"), *cert. denied*, No. 09-921, 2010 WL 390377 (U.S. Mar. 22, 2010); *Hodges v. S.C. Toof & Co.*, 833 S.W.2d 896, 901 (Tenn. 1992).

[46] *See State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408, 419-20 (2003) ("[A] more modest punishment for this reprehensible conduct could have satisfied the State's legitimate objectives, and the Utah courts should have gone no further."); *BMW of N. Am., Inc. v. Gore*, 517 U.S. 559, 584 (1996) (reversing punitive damages award because, in part, trial court failed to consider "whether a lesser deterrent would have adequately protected the interests of [] consumers"); *Cont'l Trend Res., Inc. v. OXY USA, Inc.*, 101 F.3d 634, 639-40 (10th Cir. 1996) ("In figuring harm both actual and potential harm may be considered. But it must be harm to these plaintiffs, not to others.").

compensatory damages awarded.[47]

In making your decision you must consider the instructions I have already given you and also the following:

1. The defendant's net worth and financial condition;

2. The objectionable nature of the defendant's wrongdoing, the impact of the defendant's conduct on the plaintiff, and the relationship of the parties;

3. The defendant's awareness of the amount of harm being caused to the plaintiff and the defendant's motivation in causing the harm;

4. The duration of the defendant's misconduct and whether the defendant attempted to conceal the conduct;

5. Any other circumstances shown by the evidence that bears on determining the proper amount of the punitive award.

You have already awarded the plaintiff compensatory damages for the purpose of making the plaintiff whole. The purpose of an award for punitive damages is to punish a wrongdoer and to deter misconduct by the defendant or others.[48]

Punitive damages may not be awarded if reasonable people could conclude that the defendants' conduct was lawful. Therefore, you may not award punitive damages unless plaintiff proves by clear and convincing evidence that the defendant had no arguably legitimate basis for its conduct.[49]

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[47] *See State Farm Mut. Auto. Ins. Co.*, 538 U.S. at 426 (holding that punitive damages must be "reasonable and proportionate to the amount of harm to the plaintiff and to the general damages recovered").

[48] *Tennessee Pattern Jury Instructions* § 14.56 (2009) (Punitive Damages - Amount). Defendants propose a modified version of PJI section 14.56 in order to include standards established by the United States Supreme Court, eliminate factors that are irrelevant on the facts of this case, and eliminate factors that could, on the facts of this case, lead to a disproportionate punitive damage award.

[49] *See generally State Farm Mut. Auto. Ins. Co.*, 538 U.S. at 421 ("A State cannot punish a defendant for conduct that may have been lawful where it occurred."); *Sw. Tel. & Tel. Co. v. Danaher*,

You may not award any punitive damages to protect people or punish for harm outside of Tennessee.[50]

You may not base the amount of any punitive damages award on any past, present, or future harm to anyone other than the plaintiff in this case. Any amount of punitive damages you award must be based on the defendants' conduct with respect to the plaintiff in this case.[51]

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238 U.S. 482, 490 (1915) (even if the defendant "should have known that the supreme court of the state, in the exercise of its judicial power, might hold [its conduct] unreasonable," a $6,300 civil penalty violated "fundamental principles of justice" where "the prevailing view elsewhere was otherwise"); *Satcher v. Honda Motor Co.*, 52 F.3d 1311, 1317 (5th Cir. 1995) (vacating punitive damages award in design defect case where "there is a genuine dispute in the scientific community as to" the reasonableness of the design).

[50] *See State Farm Mut. Auto. Ins. Co.*, 538 U.S. at 421-22 (2003) ("A State cannot punish a defendant for conduct that may have been lawful where it occurred. Nor, as a general rule, does a State have a legitimate concern in imposing punitive damages to punish a defendant for unlawful acts committed outside of the State's jurisdiction. Any proper adjudication of conduct that occurred outside Utah to other persons would require their inclusion, and, to those parties, the Utah courts, in the usual case, would need to apply the laws of their relevant jurisdiction. . . . A jury must be instructed, furthermore, that it may not use evidence of out-of-state conduct to punish a defendant for action that was lawful in the jurisdiction where it occurred.") (citations omitted); *BMW of N. Am., Inc.*, 517 U.S. at 585 ("While each State has ample power to protect its own consumers, none may use the punitive damages deterrent as a means of imposing its regulatory policies on the entire Nation."); *see also Clark v. Chrysler Corp.*, 436 F.3d 594, 609-10 (6th Cir. 2006) (same).

[51] *See Philip Morris USA v. Williams*, 549 U.S. 346, 354-55 (2007) ("[W]e can find no authority supporting the use of punitive damages awards for the purpose of punishing a defendant for harming others. . . . [A] jury may not . . . use a punitive damages verdict to punish a defendant directly on account of harms it is alleged to have visited on nonparties."); *State Farm Mut. Auto. Ins. Co.*, 538 U.S. at 423-24 ("A defendant should be punished for the conduct that harmed the plaintiff, not for being an unsavory individual or business. Due process does not permit courts, in the calculation of punitive damages, to adjudicate the merits of other parties' hypothetical claims against a defendant under the guise of the reprehensibility analysis . . . . Punishment on these bases creates the possibility of multiple punitive damages awards for the same conduct . . . . The same reasons lead us to conclude the Utah Supreme Court's decision cannot be justified on the grounds that State Farm was a recidivist. . . . The reprehensibility guidepost does not permit courts to expand the scope of the case so that a defendant may be punished for any malfeasance, which in this case extended for a 20-year period."); *Cont'l Trend Res., Inc.*, 101 F.3d at 639-40 ("In figuring harm both actual and potential harm may be considered. But it must be harm to these plaintiffs, not to others."); *see also Clark*, 436 F.3d at 609-10 (same).